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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/697,840

10/30/2003

David W. Wynn

MCP-5021

9284

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EXAMINER

GEORGE, KONATA M

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

08/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/697,840

Applicant(s)

WYNN ET AL.

Examiner

Konata M. George

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1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-15 and 17-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-6, 8-15 and 17-26 are pending in this application.

Request for Continued Examination (RCE)

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 16, 2007 has been entered.

Action Summary

2. The examiner acknowledge the cancellation of claims 7 and 16 and the addition of claims 23-26.
3. The rejection of claims 1-6, 8-15 and 17-22 under 35 U.S.C. 103(a) over Ratnaraj et al. in view of Singh et al. and Barry et al. is hereby withdrawn.

Response to Arguments

4. Applicant's arguments with respect to claims 1-6, 8-15 and 17-22 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-6, 8-15 and 17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratnaraj et al. (US 5,658,919) in view of Singh et al. (US 5,759,579) and Robinson et al. (US 20030049316).

Applicants claim a liquid suspension of particles of NSAID and/or acetaminophen wherein the particles are covered with one layer of a controlled release composition wherein the composition comprises as insoluble film former polymer and an enteric polymer and wherein the suspension comprises a vehicle comprising water.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Ratnaraj et al. disclose a novel suspension system containing acetaminophen (col. 2, lines 46-55). Column 4, lines 1-2 teach the system is suitable from suspending acetaminophen powder. The suspending system (examiner relates it to the vehicle as claimed by applicant) comprises xanthan gum and a mixture of microcrystalline cellulose and sodium carboxymethylcellulose (col. 2, lines 51-53). Table 1 of columns 6 and 7 disclose the addition of water to the vehicle, a glycol such as propylene glycol, sweeteners and flavoring agents.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Ratnaraj et al. do not teach the particles being coated with a controlled release composition, the composition having a therapeutic effect of least about 8 hours and the NSAID is a propionic acid derivative. It is for this that Singh et al. and Robinson et al. are joined.

Singh et al. disclose a pharmaceutical suspension system comprising finely divided pharmaceutically active compounds and liquid excipient suspension system comprising water, and the suspending agents xanthan gum and hydroxypropyl methylcellulose (col. 1, lines 4-12). Column 2, lines 30-35 teach that the active compounds can be non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesic drugs such as acetaminophen. Of the NSAIDs for use in the system propionic acid

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derivatives can be employed (col. 3, lines 3-7). Preservatives, sweeteners, and flavoring agents can be used in the system (col. 4, lines 5-10). The various examples in columns 4-7 teach the concentrations of the drug as about 3.20% and a least 40% water.

Robinson et al. disclose tablets comprising NSAID and/or acetaminophen and wherein the particles are coated with a taste masking composition. The taste masking composition can comprise an insoluble film-forming polymer (cellulose acetate or ethyl cellulose) and an enteric polymer (EUDRAGIT™ E-100) (paragraph 0021).

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Ratnaraj et al. (a suspension of acetaminophen) in view of Singh et al. (a suspension of NSAIDs) with Robinson et al. to arrive at the claimed invention. It is known that acetaminophen and NSAIDs are drugs that do not possess a pleasant taste; therefore coating these drugs to mask the taste is obvious and well known throughout the art. Therefore, one of ordinary skill would look to the coating compositions of Robinson et al. to coat the drugs of Ratnaraj et al. or Singh et al. for the purpose of masking the taste of the drugs. It is the position of the examiner that since the polymers used in taste masking the drug are the same as those claimed for controlling the release of the composition, the release profile for the active agent would also be met.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants use the phrase "less than about" or "greater than about" in the claims when describing the dry weight of the coating. It is unclear to the examiner if it is "less than", "greater than" or "about" that are being claimed.

7. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants in the claims recite the phrase "derivatives". Webster's Dictionary defines a derivative as "a substance derived from, or of such composition and properties, that it may be considered as derived from, another substance by chemical change, esp. by the substitution of one or more elements or radicals". Based on this definition it is unclear what the derivative is.

Conclusion

8. Claims 1-6, 8-15 and 17-26 are rejected.

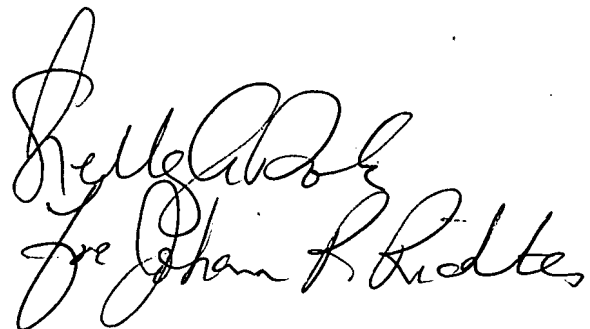
Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Technology Center 1600

The block contains two handwritten signatures. The top signature is in cursive and appears to read 'Konata M. George'. The bottom signature is also in cursive and appears to read 'Johann R. Richter'.

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600

**SHELLEY A. DODSON
PRIMARY EXAMINER**